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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,816	08/31/2001	Jay W. Grate	13129-E (50005-50)	1380

7590 10/14/2005

MCKINLEY LAW OFFICE
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EXAMINER

DO, PENSEE T

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/944,816

Applicant(s)

GRATE ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 1-41 and 57-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/19/04, 1/30/02
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group II, claims 42-56, in the reply filed on August 8, 2005 is acknowledged. The traversal is on the ground(s) that "the examiner has not set forth a prima facie case for restriction, because in the paragraph bridging pages 2 and 3 of the restriction, the examiner has admitted on the record that "the inventions listed relate to a single general concept...". This is not found persuasive because although the three inventions relate to a single general concept, such single general concept is not novel or taught in the art by Blankenstein. Other than such known concept, the three inventions are not related in any other way.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47 recites "dispersion region" which lacks antecedent support. Claim 42 does not recite a dispersion region. Please be consistent.

Claim 51 recites "the main port" in line 7, which lacks antecedent support. The selection valve does not have any "main port" as recited.

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Claim 53, which depends from claim 42, fails to provide antecedent support for these components: "the multiport selection valve, the three-way valve and the pump".

Claim 42 does not recite any of the above components.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 42-45, 50, 52, 54-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Blankenstein (US 6,432,630).

Blankenstein teaches a micro flow system comprising a fluid flow path with first and second ends and a capture zone (located on the flow channel where the magnet imposes the magnetic field) in between the first and second ends (see fig. 1, col. 12, line 63-col. 13, line 11); a fluid flow controller such as a stepper motor syringe pump that operates in a reversible direction (see col. 17, lines 58-60; col. 18, lines 5-8, lines 45-46); a magnetic field source such as a permanent magnet or an electromagnet (see col. 5, lines 60-65; col. 7, lines 55-58); and an optical detector such as a microscope (see col. 17, lines 20-35). The capture zone is free from fixed magnetizable solid matrix structure. (see fig. 1). Alternative, the system comprises a plurality of capture zones and a plurality of magnetic field sources separated from one another by a zone free of a

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magnetic field. (see fig. 13, col. 19, line 60-col. 20, line 22). The system also comprises channels for addition of liquids including magnetic particles which are equivalent to "means for providing in the fluid flow path a first mixture of plurality of solid magnetic particles dispersed in a carrier medium" (see fig. 10, components 57 and 2; fig. 11, inlet port 2; col. 18, lines 31-62). Regarding claim 46, although the magnetic field strength is not taught, it is an inherent property because Blankenstein teaches a magnetic field source as a permanent magnet or an electromagnet which are the same as that of the present invention. Regarding claim 48, Blankenstein teaches that the channel has a width of 0.1 to .55 mm, depth of 0.04 to 0.2 mm and a length of 20 mm. (see col. 4, lines 38-45). Figure 1 shows that the channel is a shape of a tube with a diameter. Base on the width and depth given by Blankenstein, the diameter of the channel would be 0.2 mm and thus falls within the range of the diameter claimed by the present invention. Regarding claim 48, Blankenstein teaches that the volumetric flow rates range from 0.1 to 200 $\mu\text{L}/\text{min}$. (see col. 4, lines 49-55). The volume in the capture region in Blankenstein is within the volume range as claimed by the present invention.

Claim 56 is rejected under 35 U.S.C. 102(e) as being anticipated by Davidson et al. (US 6,482,328).

Davidson teaches an apparatus comprising a fluid flow path means having a first and second ends and a capture zone between the first and second ends (see fig. 1-2 feed tube 12 as the flow path in fig. 2 with inlet port/first end 12a and outlet port/second end near valve 27). The portion between the two magnets is equivalent to the capture region because that is the region where the magnetic particles are captured. (see col. 5,

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lines 14-15; col. 6, lines 25-44). The apparatus also comprises of means for providing in the fluid flow path a first mixture of plurality of magnetic particles in a carrier medium (fig.2 feed tube 12); means for variably imposing a positive or negative pressure on the fluid path means to cause controlled fluid flow through the fluid flow path in a first or second direction at predetermined rates (see fig. 2 controller 20); and means for providing a fixed magnetic field that intercepts the fluid flow path means in the capture zone (fig. 2 magnets 18).

Claims 42-45, 47-54, 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Chandler et al. (International Journal of Food Microbiology, vol. 70, No. 1-2, 22 October 2001 (22.10.2001), pp. 143-154).

Chandler teaches an electromagnetic flow cell and fluidic system for automated immunomagnetic separation (IMS) of *E. coli* 0157:H7 directly from poultry carcass rinse. The apparatus or system comprises a fluid flow path, having a first and second ends with a capture region in between; a fluid flow controller to cause controlled fluid flow through the fluid flow path in a first and second direction at predetermined rates; a magnetic field source (electromagnet) or a magnet (see p. 149; second col. in the capture zone; and a detector positioned to detect a physical or chemical property in the fluid flow path. (see figure 1). Detection is on-line process monitoring (computer which is an optical detector). (see page 152, col. 1, 1st paragraph). The flow path in the capture zone has a volume of 25 ul. (see p. 147, col. 2). The flow path has a diameter of 2.1 mm (see figure 1). The pump is a syringe which can pump reversibly in fluid communication with the flow path. (see fig. 1) The controller also comprises a multiport (10 port

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selection valve) including a primary port and a plurality of secondary ports, one of the secondary ports is connected to the inlet of the flow path; a holding coil having one end connected to the primary port and the other end is connected to a three-way valve having a first port connected to the holding coil, the second to the pump and the third to a wash composition. (see fig. 1). Regarding the claim 52, since the syringe pump of Chandler functions the same way as that of the present invention, it is inherent that it is a stepper-motor driven syringe pump since Chandler teaches that the pump and the flow system are controlled by a laptop computer with a preprogram. The capture zone is free from fixed magnetizable solid matrix structures. Since the fluid flow controller of Chandler is the same as that of the present invention, it is inherent that it can provide a flow rate in the flow path up to 2500 mm/s in either direction.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blankenstein (US 6,432,630).

Blankenstein has been discussed above.

However, Blankenstein fails to teach the controller is effective to provide a flow rate in the fluid flow path ranging up to about 2500 mm/s in either direction.

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It would have been obvious to one of ordinary skills in the art to use a controller with a flow rate up to about 2500 mm/s in the flow path through routine experimentation depending on how much of the fluid sample there is to be processed. If there is a high concentration of fluid sample needed to be processed, then a higher flow rate is needed.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blankenstein (US 6,432,630) in view of Wade et al. (US 5,695,720).

Blankenstein has been discussed above.

However, Blankenstein fails to teach a multiport selective valve including a primary port and a plurality of secondary ports, wherein a first secondary port is fluidly connected to the inlet of the fluid flow path; a holding coil having a proximal end and a distal end; wherein the distal end is fluidly connected to the primary/main port of the selective valve; a three way valve having a first port fluidly connected to the proximal end of the holding coil; a second port fluidly connected to the variable speed reversible pump; and a third port fluidly connected to a source of wash composition.

Wade teaches an apparatus for flow analysis comprising a computer-controlled fluid manipulation and analysis apparatus for chemical, biochemical, and clinical analysis, sample preparation having one or more stream selection hubs with multiple ports through which microliter volumes of multiple fluid streams may be accessed, stacked, mixed and otherwise transferred by two or more pumping systems in a highly repeatable and fully software programmable manner. Figure 1 has a pump 48 connected to a three-way valve, one for a wash solution 44, one for the coil 32. The coil

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is fluidly connected to the selector valve 20 with a primary valve 16 and a plurality secondary ports 14. One of the valve 14 can be vessels containing fluids, such as sample, reagents, wash and other chemical or biochemical fluids or to detectors or to waste container or stream or to other sample processing apparatus. (see col. 8, lines 3-65; figure 1).

It would have been obvious to one of ordinary skills in the art to incorporate the apparatus of Wade into the apparatus of Blankenstein since both devices are used for the purpose of fluid processing or analysis. Both devices need a detector and use syringe pumps for controlling fluid flow. Both devices also use coil and three-way valve and are controlled by computer. Thus, one of ordinary skills in the art would have reasonable expectation of success to incorporate into the apparatus of Wade a separation channel with magnets connected to the one of the secondary ports 14 since Wade teaches that port 14 can be attached to vessels containing fluids such as sample, reagents, or other **sample process apparatus**. Such a multiport selective valve taught by Wade can organize the detector, waste chamber of the apparatus of Blankenstein into an orderly functional device.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
September 26, 2005


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09/30/05